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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/944,234	10/06/1997	VINCENT BRYAN	A8038	1173

7590

08/22/2003

SUGHRUE MION ZINN MACPEAK & SEAS, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DE 20037-3213

EXAMINER

NGO, LIEN M

ART UNIT

PAPER NUMBER

3727

DATE MAILED: 08/22/2003

49

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/944,234

Applicant(s)

KUNZLER ET AL.

Examiner

LIEN TM NGO

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 and 52-125 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 8-12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 5-7, 13-50 and 52-125 is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The Office Action (paper No. 45 issued 2/11/03) has been withdrawn and replaced by this Office action as following:

Specification

1. The amendment filed 12/4/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the disclosure of new adding paragraphs 40 (the convex surface ^{deleted} 42 of the form cutter 29 of the figs. 1 and 2 can not form a matting surface in the vertebral body that is complement to the concaval-convex shape of the endoprosthesis illustrated in figs. 4-6), the method of milling a vertebral body using the present invention drill head in paragraph 47 (the drill ^{deleted} head 20 described in fig. 2 can not form concaval-convex surfaces that mate with corresponding surfaces of an endoprosthesis described in figs 4-6), and it is not true that the cutter has a milling surface 22 having a width substantially the same as the width of the endoprosthesis in figs. 6 and 7 as described in the abstract .

Applicant is required to cancel the new matter in the reply to this Office Action.

2. The disclosure is objected to because of the following informalities: Paragraph [01] in the beginning of the specification should be deleted because this application is a CPA filed for the same present patent application 08/94343. Therefore, the priority data should not include in the specification.

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Appropriate correction is required.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The original drawings does not show every feature of the invention specified in the claims. For example, the "slot" configured through the upstanding wall of a housing disposed at the distal end of the shaft portion, which the drive means is operatively coupled to the cutter (claims 29, 72, 86, 103). *should be cancelled.*

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 29, 36, 37, 39-50, 52-66, 72, 77, 78, 82, 86, 93-96, 98, 99, 103, and 110-125 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For example:

claims 29, 72, 86, 10, ³"a slot"; ✓

claims 37, "a smooth surface"; *

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and with the bearing surface
claims 49, 62, the milling surface has a width substantially the same as the width of the insert to be implanted.

insert
claims 50, 53, 63, outwardly facing first and second milling surfaces;

claim 58, "said bearing surface is smooth"; *→ generally cited as smooth*

claim 62, "the surface of that vertebra having a contour that substantially matches the

contour of a surface of the insert to be implanted and that substantially matches the contour of the milling surface"

insert
claims 36, 77, 93, 110 "at least two milling surfaces ... and end plate";

claims 37, 78, 82, 111 "a smooth surface";

claims 98, 112, 113, "at least two milling surfaces";

claims 41, 47, 49, 62, 114, 120, 121, milling surface has a width selected to substantially match the overall width of the insert,

insert
claim 47, also "at least one broad milling surface".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 1-3, 5-7, 13-50, 52-61 and 67-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheicher (4,197,645).

In regard to claims 1-3, 5-7, and 13-24, Scheicher discloses, in figs.1-4 and 13-18, a milling apparatus or a device for preparing a space in human bone to receive an implant, which also is capable of preparing a space in a human spine to receive an insert if one desires to do so. Said milling apparatus comprises head and bone drill comprising: a drill head 11, a rotary form cutter 5, a drive means 40, elongate housing 3, said form cutter has a convex shape, a groove, and provided with a beveled gearing surface 37, the height of profile of the form cutter is approximately 9 mm, as disclosed in col.17, line 56, said drive means having a pinion gear 39, and said cutter having a support shaft 8 which forms an angle approximately 96 degrees to the drive means 40. (angle approximately 96 degrees which generally could be 90 degrees).

The statement of intended use of the device for preparing a space in a human spine to receive and insert between adjacent vertebral bodies has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Scheicher, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

In regard to claims 25-61 and 67-125, Scheicher device disclose all limitations as claimed.

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Response to Arguments

8. Applicant's arguments filed 12/4/02 have been fully considered but they are not persuasive.

In response to applicant's argument that no new matter arises from the amended specification. However, that is not found convincing as pointed out in paragraph 1 above.

In response to applicant's traverse to the 35 U.S.C 112 rejections, first paragraph, however, that is not persuasive

claims 29, 86, 103, the housing disposed at the distal end of the shaft portion has "a slot" configured... is not support in the specification. Applicant traverses that in amended fig.2 which shows slot 46. However, the slot 46 is not disposed in housing 20 at the distal end of the shaft portion.

claims 37, "a smooth surface" is not supported in the original specification. Although each of figs 1-3 illustrates the surface 31 of the housing 20 being flat and smooth, but it is submitted that one ordinary skill in the art would appreciate that it is advantageous to provide a rough surface 31 to permit the housing to stay in a stable position as it contact to a vertebrae during milling the bone.

claims 47, " at least one broad milling surface" or more than one broad milling surface is not supported in the original specification.

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claims 50, 53, 63, "outwardly facing first and second milling surfaces", even assuming the cutter including two milling surfaces 42 and 44, the two surfaces are inclined relative to one another but they are not facing to each other (see fig. 2 of the present application)

claim 58, "said bearing surface is smooth", see examiner's argument as claim 37

claim 62, the contour of the milling surface (fig. 2) does not match neither to the surface of the vertebra nor the surface of the insert (figs. 6 and 7)

claims 36, 77, 93, 98, 110, 112, 113, "at least two milling surfaces"; there are no more than two milling surfaces disclosed.

claims 37, 78, 82, "a smooth surface"; see examiner's argument as claim 37.

claims 41, 47, 49, 114, 120, 121, it is not true that the milling surface has a width substantially the same as the width of the insert to be implanted

In response to applicant's argument that the Scheicher does not disclose the limitations of the claims as applicant pointed out in the response, page 27, lines 13-20 and page 28, lines 1-12. However, that is not found convincing, because Scheicher discloses in fig. 1-4 and 13-18, a device comprising a drill head 5 (a, b and c) wherein the maximum height of the profile of the form cutter is prefer about 2.8-6 mm (distances A, B and C in fig.3, see col.17, lines 52-57) which meet limitation of claim 20. This profile height of Scheicher device is capable of milling a space between adjacent vertebrae to received an insert if one desires to do so. The form cutter has at least one milling surface being convex (see figs. 2, 5 and 23) and a support shaft 8 which form

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angle about 90 degrees to the drive means 40. Examiner notes that claim 22 requires the angle being approximately 96 degrees and it is clear to one ordinary skill in the art would consider an angle approximately 96 degrees being generally about 90 degrees.

The statement of intended use of the device for preparing a space in a human spine to receive and insert between adjacent vertebral bodies has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Scheicher, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Moreover, Scheicher disclose a milling apparatus for preparing a space in human bone to receive an implant comprising limitations substantially as claimed, therefore, the Scheicher milling apparatus is capable of preparing a space in a human spine to receive an insert if one desires to do so.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lien Ngo whose telephone number is (703) 305-0294. The examiner can normally be reached Monday through Friday from 8:00 AM to 5:00 PM.

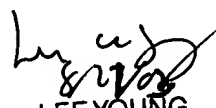
If attempts to reach the examiner by telephone are unsuccessful. The examiner's supervisor, Lee Young, can be reached at (703)308-2572. The Group FAX number is (703) 305-3579.

Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist at (703) 308-1148.

Lien Ngo

August 18, 2003




LEE YOUNG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

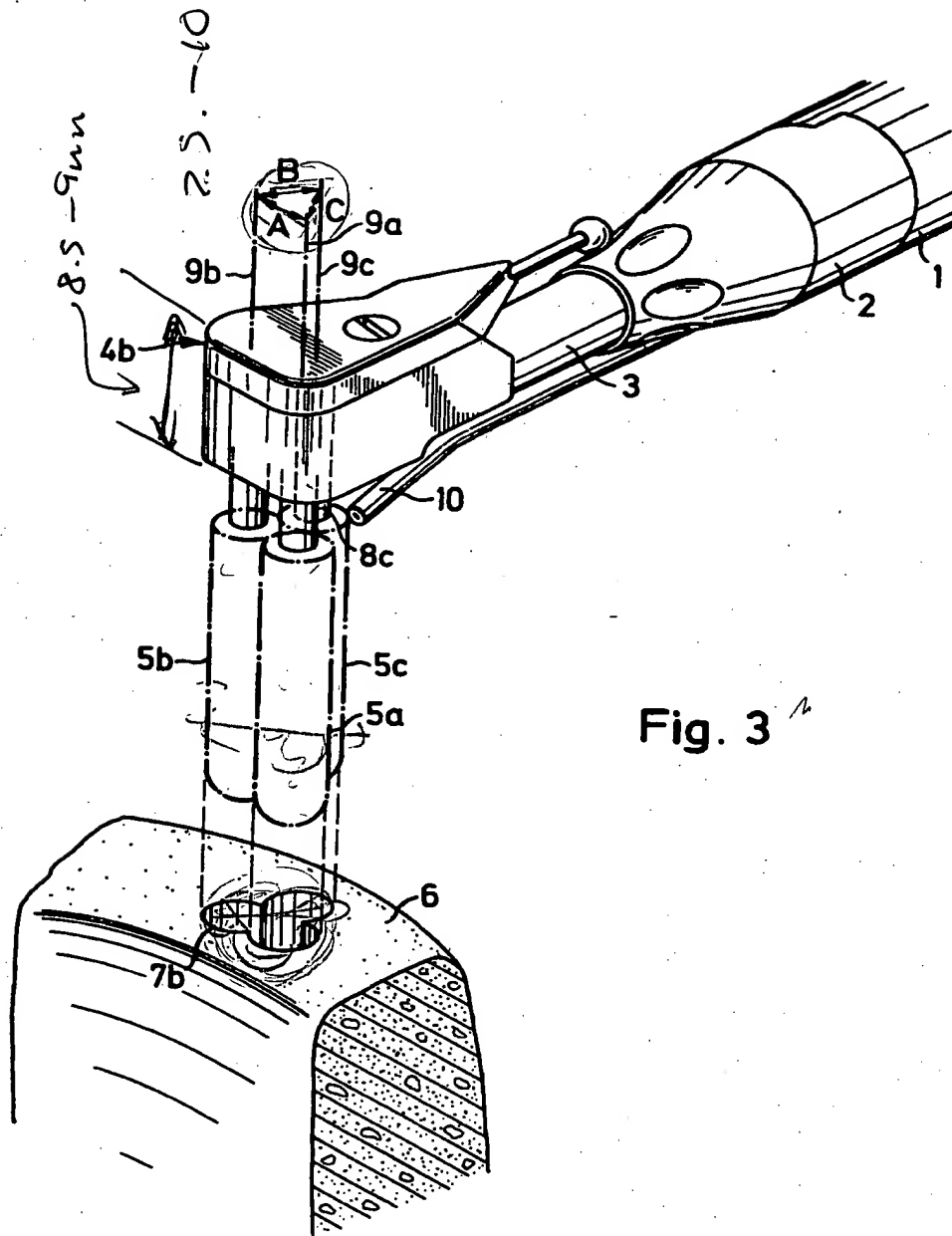


Fig. 3

